REMARKS

Claims 55, 57, 62, and 64 have been amended to clarify that the plant line is a *Brassicaceae* or *Helianthus* plant line. Claim 66 has been amended to correct a typographical error. No new matter has been introduced. Applicants respectfully request reconsideration and allowance of claims 10, 27, 29, 31-35, 37-46, and 55-70 in view of the above amendments and following remarks.

Interview Summary

Applicants thank the Examiner for the courtesy of a phone interview on January 19, 2006, with Dr. McCormick Graham and the undersigned attorney. During the interview, arguments for overcoming the enablement rejection of claims 10, 27, 29, 31-35, 37-46, and 55-70 were discussed. The Examiner asserted that Applicants' statements in the specification of how to use the claimed nucleic acids and plants were not sufficient in the absence of a working example. Applicants indicated that a working example was not necessary to enable the claimed nucleic acids, plants, and methods as mutations in the same motif of a delta-12 desaturase resulted in an altered fatty acid content.

Rejection under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 10, 27, 29, 31-35, 37-46, and 55-70 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserted that

> The rejection is proper given that the examples that Applicants point to are prophetic and do not specifically teach how the claimed nucleic acids can be used. In addition, the disclosed plants were isolated by mutagenesis and introducing mutations is not a repeatable method for obtaining a plant having a particular desired characteristic. Certainly, it is well known in the art that mutagenesis has been used to produce mutant plants. However, it is also well known in the art that it is highly undpredictable what the genotypes and phenotypes of plants will be when mutagenesis is used. Applicant has not taught how to use the claimed nucleic acids and plants, as stated in the last office action, and it would require undue experimentation to practice the claimed invention.

This rejection is respectfully traversed.

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) ("[the] examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure"). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. See also MPEP §2164.04. The Examiner has not met this burden. No reasoning has been provided as to why the statements in the specification regarding the use of the claimed nucleic acids are not sufficient to satisfy the enablement requirement. Furthermore, no evidence has been provided to support the Examiner's assertions that mutagenesis is "highly unpredictable with respect to what the genotypes and phenotypes of plants will be when mutagenesis is used."

The test for enablement is whether one skilled in the art at the time Applicants filed the present application could make and use the claimed invention from the disclosure in the specification coupled with the information known in the art without "undue" experimentation. See, for example, MPEP §2164.01. According to *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), the factual considerations that must be weighed when determining whether "undue" experimentation would be required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount of direction or guidance provided, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. All the evidence related to each of these factors must be considered, and any conclusion of lack of enablement must be based on the evidence as a whole. MPEP §2164.01(a). Thus, in contrast to the Examiner's assertions, compliance with the enablement requirement does not turn on whether an example is disclosed. In fact, the specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in

the art will be able to practice it without undue experimentation. *In re Borkowski*, 22 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). See §2164.02 of the MPEP.

In the present application, one of ordinary skill in the art could make and use the claimed nucleic acids and plants and practice the claimed methods without undue experimentation. Applicants will first address the rejection of the nucleic acids of claims 10, 27, 29, 31-34, and 66. The present specification specifically teaches how the claimed nucleic acids can be used. For example, the specification at page 13, ¶45, indicates that labeled nucleic acid probes that are specific for desired mutational events can be used to rapidly screen a mutagenized population. Furthermore, as previously indicated, the specification indicates the claimed nucleic acids can be used, for example, as markers in plant genetic mapping and plant breeding programs. Such markers may include restriction fragment length polymorphism (RFLP), random amplification polymorphism detection (RAPD), polymerase chain reaction (PCR) or self-sustained sequence replication (3SR) markers. Marker-assisted breeding techniques may be used to identify and follow a desired fatty acid composition during the breeding process. Marker-assisted breeding techniques may be used in addition to, or as an alternative to, other sorts of identification techniques. An example of marker-assisted breeding is the use of PCR primers that specifically amplify a sequence containing a desired mutation in a delta-12 or delta-15 desaturase. See, for example, the specification at page 20, ¶65. The specification also indicates in Example 14 that the claimed nucleic acids can be used to develop gene-specific PCR markers. Thus, in contrast to the Examiner's assertions, Applicants have taught how to use the claimed nucleic acids.

The specification also enables one of ordinary skill in the art to make and use the plants of claims 35 and 37-46, and practice the methods of claims 55-65 and 67-70. In particular, the specification describes mutagenesis of *Brassica* and selection of various lines in great detail. See, specification, for example, at page 7, ¶25; page 14, ¶46 through page 16, ¶52; and page 19, ¶63 through page 20, ¶64. Extensive information is provided for mutagenesis of seeds, as well as for mutagenizing plants in other stages of development. Furthermore, the specification describes a variety of compounds that can be used to induce mutagenesis. See, specification, page 15, ¶48. The specification also indicates that low mutagen doses can be used to eliminate

the occurrence of deleterious mutations and reduce the load of mutations carried by a plant such that single gene mutations can be rapidly selected. See, specification at page 17, ¶55. Thus, the specification identifies suitable mutations and provides detailed selection protocols, allowing plants containing the desired genotype and phenotype to be selected without undue experimentation.

The specification demonstrates that alterations in the His-Xaa-Xaa-Xaa-His motif of a delta-12 desaturase results in an increased oleic acid content in seed oil of plants containing such a mutation. See, Example 6, Example 9, and Example 12 of the specification with respect to A129/IMC 129. The delta-12 desaturase of IMC129 contains a Lys in place of Glu in an His-Glu-Cys-Gly-His amino acid motif. See Table XX of the specification. Oil obtained from seeds of IMC129 has an enhanced oleic acid content and a decreased linoleic acid content relative to oil obtained from seeds of Westar. See, Table IX of the specification.

One of ordinary skill in the art would expect that mutating the same motif in a delta-15 desaturase also would result in an altered fatty acid content in the seed oil, e.g., a decreased linolenic acid content as set forth in the specification at page 8, ¶29 and ¶41, based on the following. The delta-12 and delta-15 desaturases are homologous proteins. See, for example, page 153 of Okuley et al. (Plant Cell, vol. 6, 147-158 (1994), ref. KQ on Information Disclosure Statement dated April 9, 1996), which indicates that the *Arabidopsis* FAD2 (i.e., delta-12 desaturase) and *Arabidopsis* FAD3 (i.e., delta-15 desaturase) are 37.2% identical and share 58.2% homology. Twelve regions of conserved amino acid sequences, including three His-Xaa-Xaa-Xaa-His motifs, have been identified in the delta-12 and delta-15 desaturases (see, for example, Table 7 of Lightner et al., U.S. Patent No. 6,372,965, ref. AA on Information Disclosure Statement dated September 5, 2002). The delta-12 and delta-15 desaturases also participate in the same pathway in which polyunsaturated fatty acids are produced from oleic acid. Delta-12 desaturase acts on oleic acid (C18:1) to produce linoleic acid (C18:2), which in turn is acted on by delta-15 desaturase to produce linolenic acid (C18:3). See, page 8, ¶31 of the specification. Thus, based on the results in the specification and knowledge available in the art,

one of ordinary skill in the art can obtain a plant of claims 35 and 37-43 without undue experimentation.

The specification also teaches how one of ordinary skill in the art can obtain a plant containing mutations in both the delta-12 and delta-15 desaturases, as recited in claims 44-45. See, for example, the specification at page 19, ¶61, which indicates that such plants can be obtained by making genetic crosses between single mutant lines, planting seeds obtained from the cross, selfing the resulting plants, and selecting progeny seeds carrying both mutant genes. Such plants also can be obtained by further mutating a plant containing a mutation in one of the genes. For example, seeds of IMC129, which contains a mutation in the delta-12 gene, can be subjected to mutagenesis and plants selected that also contain a mutation in the delta-15 desatuase gene. See page 19, ¶62 of the specification. Plants containing a mutation in both the delta-12 and delta-15 desaturases yield a seed oil having a high oleic acid and low linolenic acid content.

Furthermore, the specification exemplies a plant comprising a full-length coding sequence of a delta-12 fatty acid desaturase gene having at least one mutation in a region encoding a Tyr-Leu-Asn-Asn-Pro (SEQ ID NO:50) amino acid motif as recited in claim 46. In particular, line Q508 contains a His residue in place of Leu in the recited motif. See page 11, ¶41, and Examples 10 and 12 of the specification with respect to Q508.

In view of the above, the specification enables one of ordinary skill to make and use the claimed plants and practice the claimed methods without undue experimentation. The Examiner is requested to withdraw the rejection of claims 35, 37-46, 55-65, and 67-70 under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 55, 57, 62, and 64 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted that recitation of "said plant line" at step (d) lacks antecedent basis. Antecedent basis for "said plant line" can be found in the preamble of claim 55 and 64. However, claims 55, 57, and 62 have been amended to recite "said

Brassicaceae or *Helianthus* plant line" and claim 64 has been amended to recite "said *Brassicaceae* plant line" in accordance with the Examiner's suggestion during the telephone interview on January 19, 2006. The Examiner is requested to withdraw the rejection of claims 55, 57, 62, and 64 under 35 U.S.C. §112, second paragraph.

CONCLUSION

Applicants respectfully request reconsideration and allowance of claims 10, 27, 29, 31-35, 37-46, and 55-70 in view of the above remarks. The Examiner is invited to telephone the undersigned if it is felt that such would advance prosecution of the application. Please apply the two-month Petition for Extension of Time fee and any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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